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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,618	04/13/2001	Karsten Rothbarth	41154	8034

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/701,618

Applicant(s)

ROTHBARTH ET AL.

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Notice to Comply

### DETAILED ACTION

Claims 1-6 are pending in the application and are addressed herein.

#### *Sequence Compliance*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, Figures 1 and 2 contain sequences which have not been assigned appropriate "sequence identifiers" (i.e., SEQ ID NOS.). Also, the sequences referred to in the claims should be given the appropriate SEQ ID NOS. so that a proper search of the claims can be performed. It is noted that the appropriate sequence identifiers for the Figures can either be in the figures or in the description of the figures in the specification; neither of which currently identifies the disclosed sequences with SEQ ID NOS. Furthermore, pages 9 and 11 of the specification and the claims disclose sequences which also require the appropriate sequence identifiers.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) in response to this action before the application can be further examined under 35 U.S.C. §§ 131 and 132. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g).

It is noted that the CRF and Sequence Listing filed 9/28/2001, which has been entered, appears to contain the appropriate sequence identifiers for all of the disclosed sequences. However, the specification has not been amended such that each sequence in the specification has the appropriate SEQ ID NO. If the CRF and Paper listing contain all the appropriate SEQ ID NOS. (as it appears), all that is needed is for applicants amend the specification such that the appropriate SEQ ID NOS. are inserted in the appropriate places in the specification. However, if the SEQ ID NOS for all disclosed sequences are not present in the CRF and Paper Listing filed 9/28/04, Applicant must submit a new CRF, new Paper Sequence List, amendment directing the entry of the material, and a copy of the attached Notice to Comply with the response.

#### *Miscellaneous*

It is noted that the instant application comprises improper dependent claims (e.g., see claims 4-6). Applicants are requested to correct the improper dependencies in reply to this

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action. Failure to correct the problem will result in the withdrawal of improper dependent claims from consideration.

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 4, drawn to a method for inducing apoptosis in cells by transfecting said cells with an expression vector comprising (a) the DNA of Figure 1 or Figure 2 or a DNA differing therefrom by one or several base pairs, the latter hybridizing with the DNA of fig. 1 or 2; or (b) a DNA related to (a) via the degenerated genetic code.

Group II, claim(s) 5 and 6, drawn to a method for inducing apoptosis in cells by stimulating the expression of endogenous C1D gene.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for a special technical feature to link claims, the special technical feature of the claims must have similar structure as well as function. In the instant case, the Groups are not linked by a special technical feature because the Group I encompasses gene therapy wherein an expression vector expresses an exogenous C1D gene product, which allegedly has a direct therapeutic effect; while Group II encompasses stimulating the expression of endogenous C1D in the target cell. The method of stimulating endogenous C1D does not utilize an expression vector which expresses an exogenous C1D gene product. As such, the different methods utilize materially (i.e., structurally) and functionally different elements which have different desired effects. Therefore, there is no special technical feature linking the claims.

3. Claims 1-3 link(s) the inventions of Groups I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the

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allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVE T. NGUYEN  
PRIMARY EXAMINER

J. Eric Angell, Ph.D.  
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